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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/743,532 | 12/22/2003 | Meir Strahilevitz | STRM 5123D5US | 7676 |

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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3761

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------|--------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/743,532 | STRAHILEVITZ, MEIR | |
| | Examiner | Art Unit | |
| | Patricia M. Bianco | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-10,13-19 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-10,13-19 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II in the reply filed on 10/20/05 is acknowledged. Claims 13-19 were directed to the invention of Group II.

Applicant cancelled claims 1, 4, 11, 12, & 20 in response to the election, as well as added new claims 25 & 26, and amended claims 2, 3, 5-10, 21, 23, & 24 to make them dependent on the elected claims.

As a result, claims 2, 3, 5-10, 13-19, & 22-26 remain pending and have been examined on the merits.

Specification

2. Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

3. The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. It

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appears that numerous trademarks have been recited without proper indication (such as ® or ™) after each. Clarification and proper indication of trademarks is required for the following: **CHELEX 100™** and **SEPHAROSE™**. These trademarks are improperly used throughout the entire specification. Correction is required.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

4. The disclosure is objected to because of the following informalities: throughout the specification applicant first refers to the tradename CHELEX 100™ and then switches to using "Chelex." Are these the same thing? If so, clarification is required.
5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

There is lack of antecedent basis for **affinity binder** in claims 13, 7, 15, 18, 22, & 26

There is lack of antecedent basis for **first portion** in claims 13, 8, & 25

There is lack of antecedent basis for **second portion** in claims 13, 6, & 25

There is lack of antecedent basis for **binding partner** in claims 13 & 25

There is lack of antecedent basis for **targeted species** in claims 13, 18, 19, & 25

There is lack of antecedent basis for **targeting species** in claims 13 & 25

There is lack of antecedent basis for **carrier** in claims 13 & 5

There is lack of antecedent basis for **binding compound** in claims 13, 10, 3, 21, 22, 25, & 26

There is lack of antecedent basis for **pathogenic species** in claim 25

6. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542. It is believed that applicant has invoked sixth paragraph with the recitation of "**regeneration means**" which is not explicitly set forth in terms of structure and materials. Appropriate correction is required.

Claim Objections

7. Claims 15 & 16 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Drawings

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description:

Fig. 5 shows reference numbers **210, 218, & 216**, which are not mentioned in the description;

Fig. 6 shows reference numbers **305 & 306** , which are not mentioned in the description.

A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 5-10, 13-19, & 22-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification as originally filed does not set forth an enabling disclosure to describe the following structures as recited in the claims: an **affinity binder**, a **first portion & a second portion**, a **binding partner**, **targeted or targeting species**, a **carrier**, and a **binding compound** with respect to the invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 5-7, 9, 13-19, 22, & 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Strahilevitz (4,813,924). Strahilevitz discloses an extracorporeal device, see figs. 6 & 7, including catheters for drawing and returning fluid from a mammal, wherein the fluid is delivered to the device, treated and then returned. The device comprises a compartment that may have a semipermeable membrane that may have a compartment with an antibody or mixture of antibodies to drugs that may be the target. The device may alternatively have a matrix having a binding species joined to it. The species may be a hapten conjugated to a carrier, a radioactive-hapten conjugate,

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an antigen, or an antibody. The device is used for exposing at least a portion of the fluid to at least a first specific affinity binding means for chemically binding at least one chemical species in the fluid to the first binding means, and means for returning to the mammal at least a fraction of the fluid. The first specific affinity binding means comprises an antibody (col. 11, lines 67-8; col. 12, lines 1-3). Strahilevitz also teaches that the a semipermeable membrane may be connected to the affinity binding means. Strahilevitz further teaches that the device may have a regenerated solution and that it may be automatically regenerated. The solution is disclosed to be a buffer, such as glycine phosphate buffer having a pH of 2.5, thereby being an acidic buffer (col. 11, line 53-col. 12, line 3). As best can be understood, the first and second binder/binding portions and first and second portions are met by Strahilevitz- see figures 1-5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 8 & 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Strahilevitz (4,813,924) in view of Liberti (4,551,435). Strahilevitz substantially discloses the invention as claimed, see rejection supra. However, Strahilevitz fails to disclose specifically that the affinity binding means be a non-immunological chemical affinity adsorbent. Liberti discloses a blood device having an adsorbent consisting of a

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non-immunospecific factor, such as rheumatoid factor or an Fc receptor. At the time of the invention, it would have been obvious to one having skill in the art to modify the device of Strahilevitz to use a non-immunospecific factor because such a factor can bind to immune complexes for subsequent removal from the blood.

12. Claims 10 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strahilevitz (4,813,924) in view of Terman (5,091,091). Strahilevitz substantially discloses the invention as claimed, see rejection supra. However, Strahilevitz fails to disclose specifically that the affinity binding means is chosen from the group of Protein A, Protein G, and C1q bound to anti-C1q antibody. However, Terman has disclosed an extracorporeal device which uses immobilized Protein A as the immunoabsorbent (col. 3, lines 58-60). At the time of the invention, it would have been obvious to one having skill in the art to modify the device of Strahilevitz to use immobilized Protein A since Protein A is used for the treatment of cancer.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 8th, 2005

Patricia M Bianco
Primary Examiner
Art Unit 3761


PATRICIA BIANCO
PRIMARY EXAMINER